

B-2) 2.5 mgm. 208% Pyridoxine HCl (B-6) 1.0 mgm. \* \* \* Vitamin B-12 (cobolamin conc.) 3.0 mcgm. \* \* \* Niacinamide 10.0 mgm. 100% Calcium Pantothenate 2.0 mgm. \* \* \* Vitamin E (dl-A-Tocopheryl acid succinate) 6.0 Int. Units \* \* \* Need in human nutrition not established. \* \* \* Packed by Vitamin Div. Dwarfies Corp. Council Bluffs, Iowa."

RESULTS OF INVESTIGATION: The article was shipped in bulk drums as described above and after its receipt at Council Bluffs, Iowa, was repacked by Dwarfies, Inc., into the bottles described above.

LIBELED: 5-5-60, S. Dist. Iowa.

CHARGE: 403(a)—while held for sale, the statement on the label of the article "Balanced Hi Protein Wafers" was false and misleading as applied to a product which was not a balanced dietary supplement and would not supply a significant amount of protein to the ordinary mixed diet, and the statement on the label of the article "Vitamin E \* \* \* need in human nutrition has not been established" was false and misleading since the need for vitamin E in human nutrition has been established; and 403(j)—the article purported to be and was represented for special dietary uses by reason of its dietary properties and its label failed to bear, as required by regulations, a statement of the percent by weight of fat and available carbohydrates in such food, and the number of available calories supplied by a specified quantity of the article.

The article was alleged also to be misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 6232.

DISPOSITION: 6-7-60. Default—destruction.

27047. Lecithin granules. (F.D.C. No. 44252. S. No. 53-491 P.)

QUANTITY: 2 200-lb. drums and 80 11-oz. ctns. at Los Angeles, Calif., in possession of Glo-Vita Corp.

SHIPPED: Between 9-29-59 and 12-10-59, from Chicago, Ill.

LABEL IN PART: (Ctn.) "Big 'B' Pure Lecithin Granules Big 'B' Pure Lecithin is a natural, pleasant tasting food product extracted from soybeans \* \* \* Two tbsp. of Big 'B' Pure Lecithin supply over 500 mg. each of Choline and Inositol and 450 mg. Phosphorus, 60% of the minimum daily requirement. Also contains poly-unsaturated fats (linoleic and linolenic). \* \* \* Big 'B' Health Foods, 6001 Whittier Blvd. Los Angeles 22, Cal. \* \* \* The Billion Dollar Meal."

ACCOMPANYING LABELING: A number of loose carton labels.

RESULTS OF INVESTIGATION: The article was shipped in bulk drums as described above and after receipt by the dealer a portion of the article was repacked into the above-mentioned cartons. Analysis showed that the article contained approximately 80 percent of the declared amount of phosphorus.

LIBELED: 2-26-60, S. Dist. Calif.

CHARGE: 402(b)(1)—while held for sale, a valuable constituent, phosphorus, had been in whole or in part omitted or abstracted from the article; 403(a)—the carton label statement "Two tbsp. of Big 'B' Pure Lecithin supply \* \* \* 450 mg. Phosphorus" was false and misleading as applied to the article which contained less than the declared amount of phosphorus; the label statements "Excellent Health Foods Supplement," "Another of the Famous Big 'B' Health Foods," "The Billion Dollar Meal," and the vignette depicting use of the article

as a meal, represented and suggested that the article would supply in significant amounts all nutrients necessary to develop and maintain health, which statements and vignette were false and misleading since the article would not supply in significant amounts all nutrients necessary to develop and maintain health; and 403(j)—the article purported to be and was represented as a food for special dietary use by reason of its vitamin and mineral content and its label failed to bear as required by regulations, the statement "the need for choline and inositol in human nutrition has not been established."

The article was alleged also to be misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 6225.

DISPOSITION: 4-8-60. Consent—claimed by Bliss Vitamin Supply, Los Angeles, Calif., and relabeled.

27048. Various vitamin products. (F.D.O. No. 44380. S. Nos. 91-023/4 P, 91-026 P.)

QUANTITY: 57 50-tablet btls. of Poundron; 40 50-tablet btls. of Toddets; and 21 individually cartoned 4-oz. btls. of Lederplex Vitamin B Complex Liquid at Taunton, Mass.

SHIPPED: Prior to March 1957, from New York, N.Y., and Pearl River, N.Y.

LABEL IN PART: (Btl.) "Poundron \* \* \* Contents: Each Tablet Contains: Whole Liver Desiccated 3 grs., Gerrous Sulfate Exsiccated 3 grs., Thiamine Hydrochloride 1.0 mg., Riboflavin 0.66 mg., Nicotinic Acid 10 mg., Vitamin B<sub>12</sub> .3 mcgs. including Aromatic Stomactic Constituents"; (btl.) "Toddets \* \* \* Each tablet contains: Methyl Cellulose 250 mg., Thiamine Chloride 1 mg., Riboflavin 2 mg., Niacinamide 10 mg., Ascorbic Acid 10 mg., Choline Bitartrate 20 mg., Inositol 5 mg."; (btl. & ctn.) "Lederplex Vitamin B Complex Liquid. Each teaspoonful (4 cc.) contains: Thiamine HCl (B<sub>1</sub>) 2.0 mg. Riboflavin (B<sub>2</sub>) 2.0 mg. Niacinamide 10.0 mg. Folic Acid 0.2 mg. Pyridoxine HCl (B<sub>6</sub>) 0.2 mg. Pantothenic Acid 2.0 mg. Choline 20.0 mg. Inositol 10.0 mg. Soluble Liver Fraction 470 mg. Vitamin B<sub>12</sub> 5.0 micrograms (as present in concentrated extractives from streptomyces fermentation)."

RESULTS OF INVESTIGATION: Analysis showed that the Poundron contained about 78 percent of the declared amount of vitamin B<sub>1</sub>, the Toddets contained about 70 percent of the declared amount of vitamin B<sub>1</sub> and about 75 percent of the declared amount of vitamin C, and the Lederplex Vitamin B Complex contained about 50 percent of the declared amount of vitamin B<sub>1</sub>.

LIBELED: 3-24-60, Dist. Mass.

CHARGE: 402(b)(1)—while held for sale, valuable constituents, namely, vitamin B<sub>1</sub> (all lots) and vitamin C (Toddets) were in part omitted or abstracted from the articles; and 403(a)—the label statements (Poundron) "Each tablet contains: \* \* \* Thiamine Hydrochloride 1.0 mg."; (Toddets) "Each tablet contains \* \* \* Thiamine Chloride 1 mg. \* \* \* Ascorbic Acid 10 mg." and (Lederplex Vitamin B Complex) "Each teaspoonful (4 cc.) contains: \* \* \* Thiamine HCl (B<sub>1</sub>) 2.0 mg." were false and misleading.

The libel alleged also that Stimavite Tastitabs were misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 6193.

DISPOSITION: 5-16-60. Default—destruction.